Remarks and Arguments

Claims 1-21, 23, 25, 26, 28-34 are currently pending. Claims 9, 12, 15, and 16 have been withdrawn. Claims 1, 4-6, 33, and 34 have been amended herein to point out the invention. New claims 35 and 36 have been added to point out the invention. Support for the amendment is found on page 6, lines 13-19; page 7, lines 17-25. No new matter has been added.

Claims 1-8, 10, 11, 13, 14, 17-21, 23, 25, 26, 28-34 stand rejected as allegedly obvious over the cited art. Each of the rejections is addressed below.

Claim Objections

Claim 9 is objected to because the Office believes the claim identifier should be "withdrawn" instead of "original." Applicants have changed the claim identifier for claim 9, thus obviating the objection.

Rejections Under 35 U.S.C. §103

1. The Prima Facie Case Requirement

The Patent and Trademark Office (PTO) bears the burden of initially establishing a prima facie case of obviousness. MPEP § 2142. MPEP § 2143 provides the standard required to establish a prima facie case of obviousness. "First there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one or ordinary skill in the art, to modify the reference or to combine what the reference teaches. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references combined) must teach or suggest all the claim limitations." The motivation to make the claimed invention and the reasonable expectation of success must both be found in the prior art, not the applicant's disclosure. *In re Vaeck,* 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991). The references must be considered as a whole and must suggest the desireability, and thus the obviousness of making the combination. *Hodosh v. Block Drug Col, Inc.,* 229 U.S.P.Q. 182, 187 n.5 (Fed. Cir. 1986); MPEP § 2141.

2. Claims 25, 26, 28, 29, 31 and 32

Claims 25, 26, 28, 29, 31 and 32 stand rejected under 35 U.S.C. §103 as allegedly unpatentable over U.S. Patent No. 6, 129,700 ("Fitz") in view of U.S. Patent No. 5,571,086 ("Kaplan"). The Office alleges that Fitz discloses a device including an outer tubular member (22), inner tubular member (16), fluid channel (24) between the outer and inner tubular members, and stent (14) mounted on the distal end of the inner tubular member (16), a discharge opening (54), or "fluid exchange aperture", at the distal end of the outer tubular member (22), which allows fluid to flow from the fluid channel (24) to a patient's lumen (column 4, lines 25-35); a plurality of such apertures (54), where the apertures (54) are located on the portion of the outer tubular member (22) covering the stent. The Office believes the stent is self-expanding (column 3, line 41) and is deployed by retracting the outer tubular member (22) (column 4, line 64), as shown in Figure 7. The Office also alleges that the inner tubular member (16) is hollow and defines a guide wire lumen (18). The Office further alleges that it is inherent from the disclosure that a port in communication with the fluid channel (24) is included to provide fluid to the channel (24).

The Office alleges that Kaplan discloses an outer catheter that can be used with a stent delivery catheter (abstract, line 7). According to the Office, Figure 13D illustrates an array of fluid exchange apertures (218) positioned along a balloon region on the catheter (200). The Office further alleges that Kaplan teaches by illustration that the array of apertures (218) can extend over a length of a catheter (200) to encompass both the proximal and distal ends of a dilation balloon. The Office believes that the balloon (280) would be analogous to the stent location area of Fitz. The Office concludes that It would have been obvious to one of ordinary skill in the art at the time the invention was made to include apertures in the outer tubular member at both the proximal and distal ends of the stent area of Fitz, as Kaplan teaches that this is another way to convey fluids to a patient's lumen from a catheter (emphasis added). Applicants respectfully traverse this rejection.

a. The Prima Facie Case Requirement Has Not Been Satisfied

The PTO has not met its burden regarding claims 25, 26, 28, 29, 31 and 32 because there would have been no motivation to combine the disclosure of Fitz with the disclosure of Kaplan. The Office states that Kaplan teaches merely another way to

convey fluids to a patient's lumen, thus both methods (i.e. the Kaplan method with apertures at the distal and proximal end of the balloon, and the Fitz method with apertures at the distal end of the tube) would successfully convey fluid to the patients lumen. Motivation to combine two references requires a perceived problem to be solved. *See Winner v. Wang*, 202 F.3d 1340, 1349, 53 U.S.P.Q.2d 1580, 1587 (Fed. Cir. 2000). A skilled artisan would not perceive a problem to be solved here because both references provide alternative acceptable approaches to the same problem. Accordingly, there would be no motivation to combine the cited references, as suggested by the Office and thus the claimed invention is not prima facie obvious. Applicants respectfully request withdrawal of the rejection.

3. Claims 1-8, 10, 11, 13, 14, 17-21, 23, 33 and 34

Claims 1-8,10,11,13,14,17-21, 23, 33, and 34 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Fitz in view of US Patent No.5,279,546 ("Mische").

The Office alleges that Fitz discloses a stent delivery catheter that includes most of the limitations of claims 1, 33 and 34, but admits that Fitz fails to include a plurality of spacers in the fluid channel. Claims 8, 10, 11, 13, 14, 17-21 and 23 depend on claim 1.

The Office alleges that Mische discloses an outer tubular member (70) and an inner tubular member (72) that define a fluid channel in between them; a plurality of spaced apart spacer members (134,136,138,140) positioned in the lumen between the two tubular members (Figure 3). The Office believes Mische discloses that the spacers provide resistance to luminal collapse and that they extend a majority of the longitudinal length of the catheter system. The Office concludes it would have been obvious to one of ordinary skill in the art at the time the invention was made to include spacers along the majority of the length of the lumen between the inner and outer tubular members of Fitz, as Mische teaches that this structure provides the catheter with resistance to luminal collapse.

a. The Prima Facie Case Requirement Has Not Been Satisfied

The PTO has not met its burden regarding claims 1-8,10,11,13,14,17-21,23,33, and 34. The prima facie case with respect to these claims fails in two respects. First, the cited references do not teach or suggest all of the claim elements. Secondly, no

motivation to combine the two references existed. Lastly, Applicants believe the Office has misinterpreted what Mische discloses. Applicants believe that Mische does not teach an inner and outer tubular member, as suggested, but rather merely teaches a single tubular member containing a plurality of lumens.

The references do not teach all of the claim limitations because neither Fitz nor Mische teach or suggest a spacer longitudinally traversing a portion of the fluid channel length. Thus there is nothing in Mische to suggest that the septal areas (column 5, lines 26-36) alleged by the Office to be spacers, traverse anything less than the full length of the catheter.

Applicants also note that providing a spacer longitudinally traversing a portion of the fluid channel length provides resistance to bending and reduced friction from sliding or relative independent movement between the inner and outer tubular members (specification, page 7, 3rd paragraph-page 8, 1st paragraph). Neither Mische nor Fitz disclose this type of spacer.

A skilled artisan would not be motivated to combine Fitz with Mische to obtain the claimed invention because Mische teaches away from the claimed invention. The Office alleges a skilled artisan would be motivated to place the septal area of Mische in the interluminal fluid passageway of Fitz. But Mische teaches away from an interluminal fluid passageway. Mische states:

> The Daniels et al. design, however, requires the use of the interluminal space as a fluid passageway, thereby complicating the construction and operation of the device. Use of the interlumenal space as a fluid passageway also may undesirably alter the handling characteristics depending upon the specific application and the degree to which the interluminal space is pressurized. (Column 1, lines 50-60).

Because Mische discloses it is disadvantageous to use the interluminal space as a fluid passageway, the skilled artisan would not be motivated to take the septal area disclosed by Mische and place it in the Fitz device with an intraluminal fluid passageway.

With respect to claims 17 and 18, the Applicants first note that these claims depend on claim 1 and thus, are not obvious in light of the arguments presented above with respect to claim 1. Moreover, the Office alleges that Mische clearly includes a surface on the spacers that is capable of receiving a thermal bonding treatment to fixedly couple the inner and outer tubular members. Applicants were unable to find any disclosure of a spacer with a surface capable of being thermally bonded in Mische. Applicants ask the Office to point out the specific paragraph where Mische teaches this aspect of the invention, or alternatively withdraw the rejection with respect to these 2 claims.

For the reasons set forth above, Applicants submit that Claims 1, 8,10,11,13,14, 17-21,23,33, and 34 are not prima facie obvious in light of Fitz combined with Mische. Accordingly, Applicants respectfully request withdrawal of the rejection.

Claim 30

The Office alleges that claim 30 is unpatentable over Fitz in view of Kaplan, as applied to claim 25 above, and in further view of US Patent No. 5,005,584; (Little). According to the Office, Fitz includes all the limiations of claim 30, except for a pressure measuring device. Little discloses a guide wire that measures fluid pressure and is capable of being used with the Fitz device. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the Little guide wire for the guide wire of Fitz, as this produces a combination that is capable of measuring fluid pressure within a passageway.

Applicants submit that the arguments set forth above with respect to combining Fitz with Kaplan apply here as well. Adding Little does not cure the defect. Accordingly, Applicants submit claim 30 is not prima facie obvious and thus respectfully request withdrawal of the rejection.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully request the reconsideration and reexamination of this application and the timely allowance of the pending claims.

Respectfully submitted

E Stewart Mittler Date: 5/13/05

E. Stewart Mittler, Esq., Reg. No. 50,316
KUDIRKA & JOBSE, LLP
Customer Number 021127
Tel: (617) 367-4600 Fax: (617) 367-4656